REMARKS

Claims 3, 4, 7, 8, 18, 31 and 33-37 are pending in the subject application. Applicants have amended claim 18 and canceled claims 31 and 33-37 without disclaimer or prejudice to applicants' right to pursue the subject matter of these claims in the future. Support for the amendment to claim 18 may be found in the specification, *inter alia*, at page 21, line 31 to page 22, line 19. Upon entry of this Amendment, claims 3, 4, 7, 8, and 18 as amended, will be pending and under Examination.

Telephone Interview

Applicants thank the Examiner for her time and courtesy extended to applicants' undersigned attorney during the telephone interview held on March 30, 2011.

During the March 30, 2011 telephone interview, applicants made the following points in response to the December 22, 2010 Final Office Action:

1. The status of subject application is not a §371 of PCT/FR99/02588 but is a §111 application which claims the benefit of PCT International Application No. PCT/FR99/02588 under 35 U.S.C. §119, in accordance with the December 7, 2004 Decision On Petition, a copy of which is attached hereto as **Exhibit A**;

2. The references listed in the specification of the subject application were previously disclosed in Information Disclosure Statements (IDS') submitted in connection with the subject application on September 17, 2007, January 22, 2008 or December 4, 2009.

3. Copending applications were listed on page 6 of applicants' response filed October 15, 2010 and in the IDSs filed on September 17, 2007, December 4, 2009 and October 15, 2010 in connection with the subject application;

4. Applicants' claimed invention is unrelated to contraception and there is no motivation provided by Jamin (1992), Martindale (1993), Bazin et al., Paris et al., and Hodgen et al. to administer a contraception regimen for hormone replacement therapy in estrogen deficient, menopausal women;

5. Applicants' claimed method recites an oral dose range of nomgesterol acetate (0.625mg to 1.25mg) which dose range is not included within and does not overlap with, the range disclosed in Blanc et al., namely, 2.5mg nomegesterol acetate;

6. Applicants' claimed invention is based on the surprising and unexpected discovery that a daily dose of 0.625 to 1.25 mg of nomegestrol acetate, in combination with 0.5 to 1.5mg of free estradiol or 1.5 to 2.0 mg estradiol esters, provides hormonal replacement therapy while preventing growth of uterine mucosa and inducing and maintaining endometrial atrophy; and

6. Contrary to the rationale set forth for the obviousness-type double patenting rejection of claims 3, 4, 7, 8, 18 and 31 over claims 1-6 of U.S. Patent No. 6,831,073, the amount and dosage of nomegesterol acetate (0.625mg to 1.25mg) in applicants' claimed method is not the same as, and does not overlap with, the dosage range of nomegesterol

acetate, namely 1.5mg to 3.75mg, recited in claims 1-6 of the '073 patent.

Based upon the preceding points made during the March 30, 2011 telephone interview, applicants understand that the Examiner agreed to reconsider the various grounds of rejection set forth in the December 22, 2010 Final Office Action.

The following is a more detailed discussion of the points made by applicants in response to the December 22, 2010 Final Office Action.

Priority

On page 3 of the December 22, 2010 Final Office Action the Examiner indicated that the specification should contain the priority data for the application because "[t]his application is 371 of PCT/FR99/02588 (10/25/1999)".

As discussed with the Examiner during the March 30, 2011 telephone interview, the application was originally filed as a §371 application, but the status of the subject application was changed to an application under 35 U.S.C. §111, as indicated in the December 7, 2004 Decision On Petition issued in connection with the subject application (see **Exhibit A**). Thus, the subject application claims the benefit of PCT International Application No. PCT/FR99/02588 under 35 U.S.C. §119.

Accordingly, applicants request that the Examiner reconsider and withdraw this ground of objection.

Information Disclosure Statement

The Examiner indicated on page 3 of the December 22, 2010 Final Office Action that the listing of references in the specification is not a

proper information disclosure statement. The Examiner indicated that 37 C.F.R. §1.98(b) requires a list of all patents, publications or other information submitted for consideration by the Office, and M.P.E.P. §609.04(a) states that "the list may not be incorporated into the specification but must be submitted in a separate paper". The Examiner concluded that unless the references have been cited by the Examiner on form PTO-892, they have not been considered.

In response, all of the references listed in the specification of the subject application have previously been disclosed to the U.S. Patent and Trademark Office in Information Disclosure Statements submitted on September 17, 2007, January 22, 2008 or December 4, 2009 in connection with the subject application. In this regard, applicants received with the December 22, 2010 Final Office Action copies of Forms PTO 1449 (Substitute) previously submitted which are initialed by the Examiner. Therefore, applicants understand that the references listed in the specification and listed on the initialed Form PTO 1449 (substitute) have been considered by the Examiner.

Copending Application

The Examiner indicated on pages 3 and 4 of the December 22, 2010 Final Office Action that applicants must bring to the attention of the Examiner information within their knowledge as to other copending U.S. applications which are "material to patentability" of the application in question.

As noted in applicants' response filed October 15, 2010, applicants understand that the Examiner is already aware of U.S. Patent No. 6,831,073 issued December 14, 2004 on behalf of Michael Lanquetin. This patent was disclosed in the Information Disclosure Statement filed September 17, 2007. On pages 4-6 of the December 22, 2010 Final Office Action, the Examiner has rejected claims 3, 4, 7, 8, 18 and 31

on the ground of obviousness-type double patenting over claims 1-6 of U.S. Patent 6,831,073.

Other Copending Applications

As indicated on page 6 of applicants' reply filed October 15, 2010 and in order to insure compliance with the duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the following copending applications or patents, the claimed subject matter of each of which concerns methods of contraception, not methods of hormonal replacement therapy.

1. U.S. Serial No. 11/649,672, filed January 3, 2007, was disclosed in an Information Disclosure Statement filed September 17, 2007. This application was published as US 2007-0281912 A1 on December 6, 2007 and this publication number was disclosed in an Information Disclosure Statement filed December 4, 2009. On July 10, 2010 U.S. Serial No. 11/649,672 issued as U.S. Patent No. 7,749,987 B2. U.S. Patent No. 7,749,987 B2 was disclosed in the Supplemental Information Disclosure Statement filed October 15, 2010.

2. U.S. Serial No. 12/079,335, filed March 25, 2008, was published as US 2008-0242650 A1 on October 2, 2008. This patent application publication number was disclosed in the Supplemental Information Disclosure Statement filed October 15, 2010.

3. U.S. Patent No. 6,906,049, issued June 14, 2005 in the name of Paris et al., was disclosed in the Information Disclosure Statement filed September 17, 2007.

Obviousness-type Double Patenting Rejection

On pages 4-6 of the December 22, 2010 Final Office Action the Examiner rejected claims 3, 4, 7, 8, 18 and 31 on the ground of obviousness-type double patenting over claims 1-6 of U.S. Patent 6,831,073 ('073 patent). The Examiner asserted that one who is familiar with the art would have been motivated to prepare compositions of estradiol ester such as the combination of estradiol valerate and nomegestrol acetate and use for the treatment for the treatment of estrogen deficiencies and to avoid osteoporosis. The Examiner asserted on page 6 of the December 22, 2010 Final Office Action that "[t]he amounts and dosages are the same as in the issued patent. The effect of this combination is considered inherent." (emphasis added).

In response, applicants respectfully traverse the Examiner's ground of rejection. Claims 31 has been canceled hereinabove without disclaimer or prejudice, thereby rendering this ground of rejection moot with respect to claim 31.

Applicants' claimed 0.625 to 1.25 mg range of nomegestrol acetate per daily dose is not the same as and does not overlap with the claimed 1.5 to 3.75 mg of nomegestrol acetate per daily dose recited in claim 1 of the '073 patent. Applicants' highest claim dose of nomegestrol acetate, i.e. 1.25mg, is lower than the lowest claimed dose of nomegestrol acetate in the '073 patent, i.e. 1.5 mg. Therefore, contrary to the Examiner's assertion, the amounts and dosagea are not the same as in the '073 patent.

In addition, claim 1 of the '073 patent is directed to a method of avoiding osteoporosis and withdrawl bleeding using a dose of nomegestrol acetate which does not overlap with the dose recited in applicants' claimed method for hormone replacement thereapy, i.e. a different, non-overlapping dose for performing a different method.

Furthermore, applicants' recited 0.625 to 1.25 mg range of nomegestrol acetate per daily dose is unobvious over claims 1-6 of U.S. Patent No. 6,831,073 because the claimed dose yields an unexpected result, namely, the surprising decoupling of the anti-estrogenic effect of nomegestrol acetate from its progestational effect, when nomegestrol acetate is administered continuously in combination with an estradiol. As indicated on page 22 of the specification, the highest percentage of atrophic endometria was found at the lowest progestative dose and could be used to prevent growth of uterine mucosa and induce and maintain endometrial atrophy.

In view of the preceding remarks, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Rejections Under 35 U.S.C. §103

As an initial matter, applicants have hereinabove canceled claim 31 without disclaimer or prejudice thereby rendering moot the grounds of rejection under 35 U.S.C. 103 with respect to claim 31.

1. Rejection Under 35 U.S.C. §103 over Jamin in view of Martindale, Bazin et al., Paris et al. and Hodgen et al.

As noted above, applicants' claimed invention relates to hormone replacement therapy for estrogen deficient, menopausal woman. This method is achieved by administering daily without interruption a composition containing from 0.5 to 1.5mg of free estradiol or 1.5 to 2.0 mg of an estradiol ester, and from 0.625 to 1.25mg of nomegestrol acetate per daily dose so as effect hormonal replacement therapy while preventing growth of uterine mucosa and inducing and maintaining endometrial atrophy.

Applicants' claimed invention is unrelated to contraception for a woman who has a normal menstrual cycle, i.e. a woman who is not menopausal.

As discussed with the Examiner during the March 30, 2011 telephone interview, applicants do not understand the relevance of the cited references which concern contraception in non-menopausal women and are confused by the Examiner's discussion of the obviousness of using applicants' claimed dosage regimen for contraception. Clearly, there is no motivation to use a contraception regimen disclosed as useful for treating non-menopausal women as hormone replacement therapy for estrogen deficient, menopausal woman.

Moreover, applicants' claimed invention provides unexpected advantages and results which could not have been predicted from the cited references.

Applicants' claimed invention is based on the surprising and unexpected discovery that a daily dose of 0.625 to 1.25 mg nomegestrol acetate, in combination with 0.5 to 1.5 mg of free estradiol or 1.5 to 2.0 mg estradiol ester, can be used as hormone replacement therapy to treat an estrogen deficient, menopausal woman while preventing growth of uterine mucosa and inducing and maintaining endometrial atrophy.

Applicants' claimed invention is further based on the surprising and unexpected discovery that when a daily dose of 0.625 to 1.25 mg nomegestrol acetate is administered, in combination with recited amounts of free estradiol or estradiol acetate, the anti-estrogenic effect of nomegestrol acetate is decoupled from the progestational effect.

In view of the preceding remarks, applicants request that the Examiner reconsider and withdraw the rejection of claims 3, 4, 7, 8, and 18

over Jamin in view of Martindale, Bazin et al., Paris et al., and Hodgen et al.

2. Rejection Under 35 U.S.C. §103 Over Plunkett et al. and Blanc et al.

As an initial matter, the Examiner asserted on page 19 of the December 22, 2010 Final Office Action that the presently claimed amount of estradiol is 0.5mg and nomegestrol 2.0 mg/dose. As discussed with the Examiner during the March 30, 2011 telephone interview this is not correct. Applicants' claimed range of nomegesterol acetate per daily dose is 0.625 to 1.25mg, i.e. a range which does not include, or overlap with, 2.0mg.

As acknowledged by the Examiner on page 19 of the December 22, 2010 Final Office Action, Plunkett et al. do not disclose use of nomegestrol acetate at all, let alone use of 0.625 to 1.25 mg nomegestrol acetate per daily dose in hormone replacement therapy.

Blanc et al. disclose use of nomegestrol at a dose of 2.5 mg/day, which does not overlap with the 0.625 to 1.25 mg range recited in applicants' claimed method. (As noted above, the Examiner has incorrectly stated on page 19 of the December 22, 2010 Final Office Action that a 2.0 mg nomegestrol acetate is presently claimed.)

Blanc et al. further disclose an oral estradiol dose of 2.0mg versus the currently claimed oral dose of 0.5 to 1.5mg of free estradiol.

Thus, applicants' claimed method recites for nomegestrol acetate an oral dose range which is not included within, and does not overlap with, the range disclosed in any of the cited references. Accordingly, there is no basis for a finding of prima facie obviousness.

Moreover, as noted above, applicants' claimed invention provides unexpected advantages and results which could not have been predicted from the disclosures of the cited references.

In view of the preceding remarks, applicants request that the Examiner reconsider and withdraw the rejection of claims 3, 4, 7, 8, 18 over Plunkett et al. and Blanc et al.

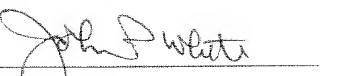
Conclusion

For the reasons set forth, applicants maintain that the grounds of the Examiner's objections and rejections have been overcome and respectfully request that the Examiner reconsider and withdraw these grounds of objection and rejection and allow pending claims 3, 4, 7, 8 and 18, as amended.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fees, other than the $490.00 fee for a two-month extension of time and $810.00 fee for filing the Request For Continued Examination which this Amendment accompanies are deemed necessary. The undersigned herein authorizes the Patent Office to charge the amount of $1,300.00 to Deposit Account No. 03-3125. Moreover, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

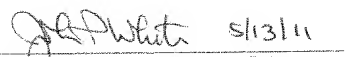
Respectfully submitted,



John P. White
Registration No. 28,678
Attorney for the Applicants
Cooper & Dunham LLP
30 Rockefeller Plaza
20th Floor
New York, New York 10112
(212) 278-0400

Certificate of Transmission

I hereby certify that this correspondence is being transmitted via the Electronic Filing System (EFS) to the U.S. Patent and Trademark Office on May 13, 2011.



John P. White Date
Reg. No. 28,678

07 DEC 2004

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
www.uspto.gov

DENNISON, SCHULTZ, DOUGHERTY & MACDONALD
1727 KING STREET
SUITE 105
ALEXANDRIA VA 22314

In re Application of
PARIS et al.
Application No.: 09/423,109
Attorney Docket No.: GEI-073
For: HORMONAL COMPOSITION BASED ON A PROGESTATIONAL AGENT AND AN OESTROGEN AND USE THEREOF

DECISION

This decision is in response to applicants' "PETITION UNDER 37 CFR § 1.182" filed via facsimile transmission on 20 July 2004 in the United States Patent and Trademark Office (USPTO).

BACKGROUND

On 25 October 1999, applicants filed international application PCT/FR99/02588, which did not designate the United States of America.

On 29 October 1999, applicants filed a TRANSMITTAL LETTER (FORM PTO-1390) for entry into the national stage in the United States which was accompanied by, *inter alia*, the U.S. Basic National Fee, a declaration of the inventors, and a translation of the international application into English including a specification and claims.

On 12 June 2001, applicants submitted a new declaration of inventors.

On 02 August 2001, the USPTO mailed a NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 (Form PCT/DO/EO/905) indicating, *inter alia*, that the oath or declaration does not comply with 37 CFR 1.497(a)-(b) because it failed to identify the application to which it was directed.

On 08 August 2001, applicants submitted a response to the Notification of Missing Requirements mailed 02 August 2001 urging that the declaration filed 12 June 2001 did correctly identify the application to which it was directed.

On 26 October 2001, a decision was mailed vacating the Notification of Missing Requirements mailed 02 August 2001 and indicating that while the declaration filed 29 October 1999 failed to correctly identify the application, the declaration filed 12 June 2001 did correctly

identify the application.

On 16 November 2001, a NOTIFICATION OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C. 371 (Form PCT/DO/EO/903) was mailed indicating that the application was accepted under 35 U.S.C. § 371.

On 20 July 2004, applicants filed the instant "PETITION UNDER 37 CFR § 1.182" via facsimile transmission. The petition requests that the application be converted from an application filed under 35 U.S.C. 371 to an application filed under 35 U.S.C. 111(a).

DISCUSSION

Because the international application failed to designate the United States, applicant is not entitled to rely on the papers filed 29 October 1999 to enter the national stage in the United States. The transmittal letter of 29 October 1999 was clearly an application for a United States patent. Applicant erred in identifying the application as a national stage application. The application papers contained all the elements necessary to obtain a filing date under 35 U.S.C. 111(a) and 37 CFR 1.53(b). Since applicant cannot proceed under 35 U.S.C. 371 and applicant has filed the necessary papers under 35 U.S.C. 111(a), it is appropriate in this instance to grant applicants' petition to accept the papers filed on 29 October 1999 as an application filed under 35 U.S.C. 111(a).

Applicant is reminded that in order to perfect the claim for priority under 35 U.S.C. 119, applicant must submit certified copies of the priority documents.

CONCLUSION

For the reasons set forth above, the petition under 37 CFR 1.182 is **GRANTED**.

The NOTIFICATION OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C. 371 mailed 16 November 2001 is hereby VACATED.

Please direct further correspondence with respect to this matter to Mail Stop PCT, Commissioner for Patents, Office of PCT Legal Administration, P.O. Box 1450, Alexandria, Virginia 22313-1450, with the contents of the letter marked to the attention of the Office of PCT Legal Administration.

This application will be forwarded to the Office of Initial Patent Examining for processing as an application under 35 U.S.C. 111(a) having a filing date of **29 October 1999**.

Daniel Stemmer
Legal Examiner
PCT Legal Affairs

Office of Patent Cooperation Treaty
Legal Administration
Telephone: (571) 272-3301
Facsimile: (571) 273-0459